

REMARKS

Claims 1 and 35-46 will be pending upon entry of the current amendment. Claim 1 has been amended, and support for the amendment can be found in the original claims and in the specification at, for example, page 11, line 22 – page 12, line 3. New claims 35-46 are supported by the original claims and by the specification. No new matter has been added.

35 U.S.C. § 112, ¶ 1

Claim 1, as filed with the present application, was rejected as failing to comply with the written description requirement (Office action at pages 2-4).

In view of the present amendment, Applicants respectfully ask that the Examiner reconsider and withdraw this ground for rejection. Claim 1, from which the new dependent claims depend or ultimately depend, has been amended to recite each of the required agents (the first agent and the second agent) with greater particularity. More specifically, claim 1 now requires that the first agent include a mutant IL-15 polypeptide and further recites a functional limitation that must be fulfilled by that polypeptide. Claim 1 now also requires that the second agent include an IL-2 polypeptide. As described in the specification, either of these polypeptides can be fused to the Fc region of an immunoglobulin. These agents are well described in the specification. The Examiner's attention is kindly directed to the specification at pages 11-18. The agents are also described in the Summary of the Invention, and they are featured in the Examples, beginning at page 33. For example, the construction of a mutant IL-15 polypeptide is described at pages 37-38, and the construction of a mutant IL-15/Fc polypeptide is described at pages 39-40. Further, IL-15, IL-2, and Fc regions of immunoglobulins were known in the art at the time the present application was filed. In fact, a mutant IL-15 polypeptide was described in U.S. Patent No. 6,001,973. Accordingly, the present specification would have conveyed to one of ordinary skill in the art that the present inventors, at the time their application was filed, had possession of compositions containing the agents now claimed. Applicants have described – particularly in view of the present amendment – much more than a mere wish or plan for obtaining the composition they now wish to claim.

Claim 1, as filed with the present application, was also rejected as failing to comply with the enablement requirement (Office action at pages 4-5). The Examiner states, "the instant specification does not disclose a therapeutic composition which comprises an agent that target IL-15R and one that targets IL-2R, neither does the specification teach how these components can be attached together" (Office action at page 5). For the sake of clarity, Applicants wish to point out that there is no requirement in the present claims that the agents required be "attached together".

Further, and in view of the present amendment, Applicants respectfully ask that the Examiner reconsider and withdraw this ground for rejection. The Examiner states, "Claim 1 is drawn to a therapeutic composition comprising a first agent that targets an IL-15R and a second agent that targets an IL-2R" (Office action at page 4). In reviewing the factors to be considered, the Examiner correctly notes that one of these is the breadth of the claims. As noted above, claim 1, from which the new dependent claims depend or ultimately depend, has been amended to recite each of the required agents (the first agent and the second agent) with greater particularity, and the Examiner is asked to consider the revised scope of the claim.

The Examiner also correctly referred to the presence or absence of working examples. Applicants have taught how to make and use the first and second agents recited in the present claims, and there is no reason why one of ordinary skill in the art could not now do the same. Additional factors, such as the quantity of experimentation necessary, the nature of the invention, the state of the prior art, and the relative skill of those in the art, also weigh in favor of enablement, particularly given the present scope of the claims. IL-15 and IL-2 are not new polypeptides, they are well known in the art and can be made using routine molecular biology techniques. It is well within the abilities of one of ordinary skill in the art to make and use the agents now recited in the claims; the level of skill in the art is high. Moreover, some experimentation is permitted. The test for undue experimentation is not merely quantitative. A considerable amount of experimentation is permissible if it is merely routine or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. MPEP at 2164.06 citing *In re Wands*, 858 F.2d

731 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489 (CCPA 1976)). Accordingly, the subject matter of the present claims is enabled.

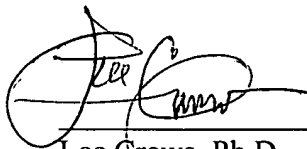
CONCLUDING REMARKS

Initialed IDS: Applicants appreciate the Examiner's comment that the information disclosure statements submitted on December 12, 2003, August 23, 2004, and January 30, 2006 have been considered (Office action at page 2). In the 1449 form attached to the present Office action, the U.S. patents and foreign patent documents or published foreign patent applications (on sheet 1 of 4) were not initialed by the Examiner. Applicants respectfully request an initialed copy.

Enclosed is a Petition for Extension of Time and a check for the required fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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